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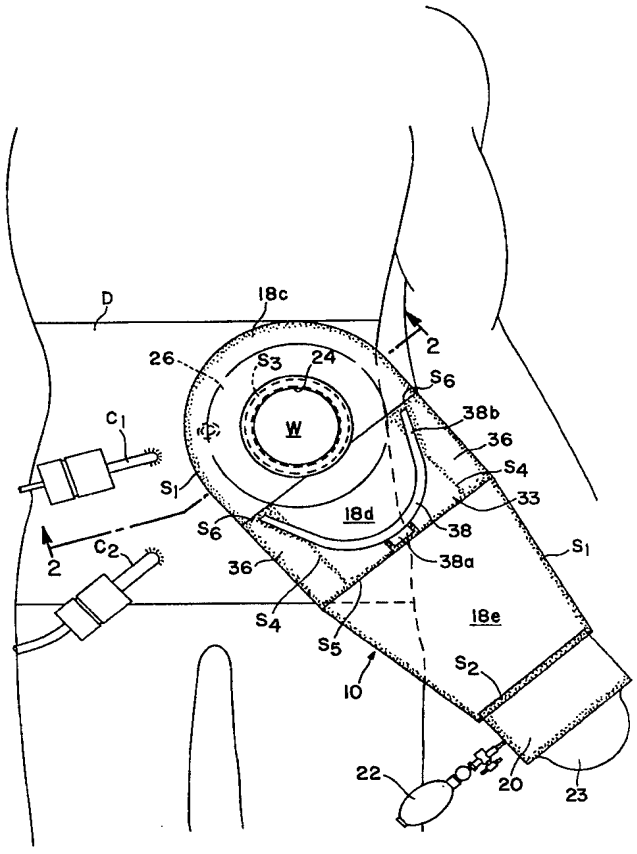
(57) Abstract

This invention is an apparatus and method for hand assisted minimally invasive laparoscopic surgery which allows for palpation and biophysical feedback within a sterile environment. A sleeve (18) provides a sealed chamber communicating with entry (23a) and exit openings (24) for access to a wound (w) and port (34) for introducing surgical instruments within easy reach of the hand.



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APPARATUS AND METHOD FOR USE IN SURGERY

Field of the Invention

The present invention relates generally to apparatus and method for use in surgery, and more particularly to a novel and improved surgical apparatus and method for permitting hand-assisted laparoscopic surgery and like minimally invasive procedures while maintaining a sterile asceptic environment.

Background of Invention

Open surgery, in general, has been preferred by surgeons since it allows both hands access to the body cavity for bio/physical feedback through palpation of organs within the cavity. However, the relatively large incisions required can be traumatic for the patient and the healing process lengthy.

Many of these operations are now possible with minimally invasive laparoscopic surgical techniques using trocar and cannula assemblies, but they are not widely performed by surgeons trained only in conventional surgery. However, not all surgeons have the highly specialized training and experience needed to perform the required critical surgical tasks with trocar and cannula assemblies while observing a remote TV image of the abdominal cavity under conditions of pneumoperitoneum.

For example, in removing a dysfunctional organ or tissue from the abdominal cavity, the peritoneum must be cannulated at precisely located sites for insufflating the cavity and for inserting an endoscope and other surgical instruments. Consequently, palpation and bio/physical feedback is not possible because there is no incision for the surgeon's hand to gain access to the cavity.

Summary of the Invention

Accordingly, it is an object of the present invention to provide a surgical apparatus suitable for hand-assisted minimally invasive surgery which allows for palpation and biophysical feedback while retaining a controlled environment.

Another object of the invention is to provide a surgical apparatus which enables surgeons already trained in conventional open surgery to perform hand-assisted laparoscopic surgery with minimal additional training.

Another object is to provide a surgical apparatus which extends the range of operations that can be performed with relatively small incisions and minimal trauma to the patient.

Still another object is to provide a surgical apparatus which enables hand-access to an insufflated cavity without loss of pressure, which offers minimal risk of damage to the immune system, and which shortens the healing time and stay in a hospital.

A further object is to provide a surgical apparatus which can be easily applied to a patient for maintaining a sterile aseptic environment at the operating site.

A further object is to provide an easily operated cuff for positively sealing around an arm or instrument extending through an entry opening of a surgical enclosure.

Another object of the invention is to provide a gas-impervious sleeve for hand-assisted surgery in which conventional instruments can be inserted under conditions of pneumoperitoneum within easy reach of the surgeon's hand.

Still another object of the invention is to provide a surgical apparatus which is suitable for hand-assisted surgery under conditions of pneumoperitoneum, and which can be quickly disconnected and reconnected around the

site of an incision to accommodate brief interruptions in the course of an operation.

A still further object of the invention is to provide a surgical apparatus suitable for maintaining a sterile aseptic environment in the immediate vicinity of a wound during a surgical procedure initiated under emergency conditions at a field station and subsequently while the patient is being transported to a more fully equipped aseptic operating room environment where the surgical procedure can be completed.

A still further object is to provide a method for performing hand-assisted laparoscopic surgery.

These and other objects and novel features of the invention are accomplished with a surgical apparatus which is attached to a patient's body during surgical procedures for permitting a surgeon's hand access through an incision while maintaining an isolated and controlled environment in the abdominal cavity. One preferred embodiment comprises a sleeve having an entry opening at one end for receiving a hand and/or instrumentarium, an exit opening at the other end with an adhesive seal around the incision accessing a cavity in a patient's body. The entry opening is sealed by an inflatable cuff around the surgeon's arm to maintain a controlled environment within the sleeve when in use. A normally closed duckbill-like gas lock between the openings provides an antechamber for retaining pressure and environmental integrity in the abdominal cavity when the entry opening is breached. A separate wound protector may be installed at the exit opening and extend through the incision.

In other embodiments, the entry opening is sealed by an adjustable tie clamp which tightens the sleeve around the arm; the sleeve provides a clear path between the entry and exit openings; the entry opening is sealed by a

flexible cuff which closes around the arm by twisting one end relative to the other; the entry opening is sealed by flange on the open end of a surgeon's glove engaging a flange at the entry opening; and a integral wound protector is sealed around the exit opening for extending through an incision for lining the wall of the wound.

Another embodiment includes access ports with duckbill check valves in the sleeve near the incision which allow laparoscopic and other surgical instruments to be introduced or removed from the sleeve without losing pneumoperitoneum or sterile integrity at the site. Still another embodiment, has two sleeves communicating with a transparent dome-shaped envelope for receiving both hands. The envelope is completely closed except for an opening in the bottom side which adhesively seals to the patient around the operating site, and access ports with duckbill check valves extending into the top of the envelope for instruments to be passed in and out during surgery. A further embodiment includes a short sleeve with a quick-disconnect ring and an adhesive flange at a distal end opening which seal around the outer end of a wound protector emplaced in the incision. A cuff at the proximal end opening seals the sleeve around the arm of the surgeon, and instrument access ports with duckbill check valves maintain pneumoperitoneum and sterile integrity at the incision while the sleeve is connected to the wound protector during surgery.

Brief Description of the Drawings

The foregoing and other objects, novel features and advantages of the invention will become more apparent from the following description when taken in conjunction with the accompanying drawings wherein:

FIG. 1 represents first preferred embodiment of a surgical apparatus with an integral inflatable cuff and

separable wound protector according to the invention applied to the anterior wall of an insufflated abdomen of a patient undergoing laparoscopic surgery;

FIG. 2 is a view in transverse cross section of the embodiment of FIG. 1 taken along the line 2-2;

FIG. 3 is a view in longitudinal cross section of the surgical apparatus of FIG. 1;

FIG. 4 is an exploded isometric view of principal components of the surgical apparatus of FIG. 1;

FIG. 5 illustrates the wound protector of FIG. 1 compacted in a sealed wrapper;

FIG. 6 illustrates the surgical apparatus of FIG. 1 folded flat in a sealed wrapper;

FIG. 7 represents a typical surgical template applied to the abdomen preceding laparoscopic surgery of FIG. 1;

FIG. 8 is a plan view of a proximal end portion of the surgical apparatus of FIG. 1 with an integral tie clamp cuff according to the invention;

FIG. 9 is a view in transverse cross-section of the tie clamp cuff taken along the line 9-9 of FIG. 8;

FIG. 10 is a radial cross section of the tie clamp cuff taken along the line 10-10 of FIG. 9;

FIG. 11 is an enlarged end view of a latch of the tie clamp cuff taken along the line 11-11 of FIG. 8;

FIG. 12 is a view in cross section of the latch taken along the line 12-12 of FIG. 11;

FIG. 13 is a plan view of a second preferred embodiment of the surgical apparatus with clear passage between entry and exit openings according to the invention;

FIG. 14 is a view in longitudinal cross section of the embodiment of FIG. 13;

FIG. 15 is a plan view of the embodiment of FIG. 13 with a twistable cuff according to the invention;

FIGs. 16A, 16B and 16C are perspective views of the twistable cuff of FIG. 15 in different positions of use;

FIG. 17 is a perspective view of the embodiment of FIG. 15 in actual use;

FIG. 18 is a perspective view of the embodiment of FIG. 13 with a glove cuff at the entry opening according to the invention;

FIG. 19 is a view in longitudinal cross section of the distal end of the embodiment of FIG. 13 with an integral wound protector according to the invention as applied to the abdomen of a patient;

FIG. 20 is a perspective view of a third preferred embodiment of a surgical apparatus according to the invention suitable for minimum invasive abdominal surgery;

FIG. 21 is an exploded isometric view in flat layout of principal components of the embodiment of FIG. 21;

FIG. 22 is a longitudinal cross-sectional view of the distal end of the embodiment of FIG. 21 taken along the line 3-3;

FIG. 23 is a view partially in cross-section of a fourth preferred embodiment of the surgical apparatus according to the invention which is especially suitable for use with both hands or under emergency field conditions; and

FIG. 24 is a view partially in cross-section of a fifth preferred embodiment of the surgical apparatus according to the invention having a quick-disconnect sleeve.

Description of the Preferred Embodiments

Referring now to the drawings wherein like reference characters denote like or corresponding parts throughout the several views, there is shown in FIGs. 1-3 a first embodiment of a surgical apparatus 10 according to the

invention. The apparatus 10 is shown adhered to an incise drape D with fenestration over a wound W in an insufflated abdominal cavity A of a patient. Cannulas C_1, C_2 extending into the cavity provide lumens for instrumentarium such as a trocar, insufflator, laparoscope and irrigator. Of course, if a surgical drape is not required, the apparatus can be adhered directly to the patient's skin.

In brief, the apparatus 10 comprises an outer sleeve 18 having a distal portion 18c adapted to be positioned in proximity with a patient's body and a proximal portion 18e remote from the body. An axial entry opening 23a is provided at the proximal end 18e of the sleeve, and an lateral exit opening 24 is provided at the distal end 18c of the sleeve. A first sealing means to be described is provided for sealing the exit opening 24 at the distal end of the sleeve, and a second sealing means to be described is provided for sealing the entry opening 23a at the proximal end of the sleeve 18. A third sealing means to be described is provided in the sleeve for forming a valved chamber in communication with the exit opening 24. As best seen in Fig. 1, the surgical apparatus 10 comprises an elongate outer sleeve 18 preferably made of a thin, transparent, gas-impermeable plastic sheet sufficiently supple for maneuvering ease. A material found suitable for this purpose is a heat-sealable 3-mil polyolefin such as Saranex® Film 2090 by The Dow Chemical Co. In a flat layout, sleeve 18 is constructed of congruent top and bottom panels 18a and 18b, respectively, defining a rounded distal section 18c, a straight intermediate section 18d and a tapered proximal section 18e. Panels 18a and 18b are heat-sealed together along a perimetric seam S_1 of section 18c and along the opposite sides of sections 18d and 18e. The proximal edge of tapered section 18e is heat sealed by a

seam S_2 around an inflatable cuff 20 which is sealingly compressed in a toroidal shape around the surgeon's arm by a hand-operated elastic bulb inflator 22 to provide the second sealing means around the entry opening 23a of the proximal end of the sleeve 18. A tab 23 extending from the proximal end of cuff 20 provides a convenient grip for pulling the cuff over the hand and arm. A lateral exit opening 24 is centrally located in rounded section 18c of bottom panel 18b and is sized to permit a surgeon's hand to pass into wound W. An annular flange 26, preferrably of like material as sleeve 18 but of 4-mil thickness, is heat-sealed to the exposed side of bottom panel 18b by a seam S_3 around exit opening 24. An adhesive 28 (FIG. 4) on the lower exposed side of flange 26 is completely covered prior to use by overlapping peel-off strips 30. When adhered to the patient's body, the flange 26 provides the first sealing means at the distal end of the sleeve 18. A suitable non-toxic, biocompatible adhesive found especially suitable for hypersensitive skin is an acrylate polymer, such as IT8-59-A by Tolas Health Care Packaging of Feasterville, Pennsylvania, having a thickness of 0.002 in., peel adhesion 8 to 10 lb/in^2, shear resistance of 1-2 hours at 1 kg/in^2, and tack 1250 g/cm^2.

The abdominal wall L and peritoneum P around wound W are protected from exposure to diseased tissue and non-sterile material during surgery by a wound protector 12. As best seen in FIGs. 2 and 3, the wound protector 12 comprises a thin flexible tube 13 and flexible O-rings 14 and 16 at opposite ends thereof. Tube 13 is longitudinally stretched over the entire peripheral surface of wound W by O-rings 14 and 16 which are expanded, respectively, over the internal edge surface of wound W and the inside surface of sleeve 18 around exit opening 24. Tube 13 is preferably made of a supple

material impermeable to gases and microorganism-bearing fluids, and may be interiorly coated with a lubricant O-rings 14 and 16 are made of a compliant material such as silicon.

According to this embodiment of the invention, a third sealing means is provided in the sleeve 18 intermediate the first and second sealing means but closer to the distal end of the sleeve 18. To this end, the third sealing means includes an inner gas lock, or duckbill check valve 32 constructed of congruent upper and lower panels 32a and 32b, respectively, extending athwart straight section 18d and heat-sealed by seam S_1 along opposite sides thereof and by seams S_4 parallel-spaced from seam S_1 to form a normally closed aperture 34 (FIG. 3) of size sufficient for the surgeon's hand to pass through. The proximal edges of panels 32a and 32b are sealed, respectively, to top and bottom panels 18a and 18b along a seam S_5. Between seams S_1 and S_4, seam S_5 and a seam S_6 also seal, respectively, the distal and proximal edges of panels 32a and 32b together with both top and bottom panels 18a and 18b forming thereby pockets 36 on both sides of opening 33 and defining a gastight chamber C.

The distal end of aperture 34 is biased in a normally closed position by tension applied to opposite sides of check valve 32 by a bow-shaped stay 38 made of a thin strip of flexible material such as 30 mil thick high density polyethylene. A tab 38a extending from stay 38 intermediate opposed ends 38b thereof is heat-staked to the middle of panel 32a adjacent the proximal end thereof, and opposed ends 38b are respectively heat-staked in pockets 36 with the sides slightly bent in deflection toward panel 32b. Thus, gas lock 32 acts like a duckbill check valve to provide a sealed chamber C at wound W by restricting flow of insufflating gas from the

area around wound W while the surgeon's hand or an instrument is being inserted or withdrawn through cuff 20. The interior of sleeve 18 and check valve 32 may be coated with a lubricant to reduce the friction and ease movement of the hand through port 34.

The size of surgical apparatus 10 may be varied to suit requirements. A typical sleeve 18 with inflatable cuff 20 is approximately 600 mm long, 240 mm wide at the distal and intermediate sections 18c and 18d, and 150 mm wide at the proximal end of section 18e. The diameters of exit opening 24 and OD of flange 26 are in the ranges of 8 mm - 110 mm and 200 mm - 240 mm respectively, and the width of check valve 32 is in the approximate range of 80 mm - 110 mm. The diameter and length of wound protector tube 13 are in approximate ranges of 10 mm - 200 mm and 30 mm - 90mm, respectively. Specific dimensions are determined according to the surgical procedure involved.

The apparatus 10 is conveniently stored in a sterile package. As best seen in FIGs. 5 and 6, prior to their use, the surgical apparatus 10 and wound protector 12 are separately folded in a flat form and stored in sealed packets 40 and 41, respectively. For example, a packet 40 containing wound protector 12 includes an inner bag 42 closed by a peel-seal flap 42a inserted within an outer bag 44 which is also closed by a peel-seal flap 44a. Surgical apparatus packet 41 is similarly contained in an inner bag 45 which is closed by a peel-seal flap 45a, and an outer bag 46 closed by a peel-seal flap 46a. Labels 48 affixed to each of packets 40 and 41 identify the contents and other information relevant to its use.

A method of using the surgical apparatus of FIG. 1, by way of illustration in a hand-assisted laparoscopic abdominal operation, is as follows. The abdomen is routinely prepared with antiseptics and dried, and a

surgical template T such as shown in FIG. 7 is aligned on the abdomen relative to the umbilicus according to indicia printed on the template. Using a skin marker pen, incision and trocar/cannula puncture sites #1 and #2 as noted on the template are traced on the abdomen. The template T is removed and a transparent incise drape D adhered to the abdomen area. A muscle-split is made with a scalpel at the incision site, fat extracted if necessary, and the peritoneum incised. Protector 12 is placed in wound W by squeezing O-ring 14 into a tight ellipse and inserting it lengthwise through the incision until O-ring 14 expands inside the peritoneum and O-ring 16 overlaps the outside of drape D around the wound.

The surgeon's hand, which may be lubricated with any extracted fat, is inserted through wound protector 12 into the abdominal cavity for guiding trocars/cannulas C_1 and C_2 safely around internal organs as they are inserted at the sites indicated. When cannulas are in place, the hand is removed and surgical apparatus 10 is placed with fenestration over the wound. The hand is re-inserted through cuff 20 into sleeve 18 for drawing outer O-ring 16 through opening 24 and allowing it to expand inside sleeve 18 around the opening. Strips 30 are then peeled off of adhesive 28 enabling flange 26 to be pressed onto incise drape D with the entry opening of sleeve 18 oriented according to a surgeon's preference.

With the hand passed through cuff 20, inflator 22 is operated to seal around the surgeon's forearm. An insufflator is then connected to one of cannulas C_1 or C_2 to create pneumoperitoneum, and a telescope and other laparoscopic instruments inserted through the lumens as needed.

The hand may then be removed or re-inserted in sleeve 18 during the surgery with no significant loss of insufflating pressure in the abdominal cavity. Of

course, if an organ or tissue suspected of infection is removed from the abdominal cavity, surgical apparatus 10, wound protector 12 and gloves should be replaced before re-entering the abdominal cavity to avoid cross-contamination.

Upon completing an operation, insufflation may be discontinued and the abdominal cavity depressurized. Wound protector 12 is simply removed by inserting a finger through its opening and gripping one edge of O-ring 14 and pulling it through the wound. The wound may now be closed according to conventional procedures.

Other types of structures may be utilized as the second sealing means in the present invention. Referring to FIGs. 8-11, there is shown another entry sealing means for the surgical apparatus of FIG. 1. Sleeve 18 includes a tie clamp cuff indicated generally by the reference number 50 comprising a cover strip 52 with edges heat-sealed along parallel spaced seams S_7 and S_8 to a proximal end portion of sleeve 18. The ends of strip 52 are spaced apart and form with sleeve 18 a covered track for sliding a tie 54 lengthwise. Tie 54 includes a finger grip 56 and a latch 58 which are exposed between the ends of strip 52 and are connected by a U-shaped strip 60 in the covered track. The two sides of strip 60 have serrated ends 60a projecting toward sleeve 18 to provide greater flexibility for closing tie 54 around an arm or instrument. An elastic pad 64, preferably of plastic foam, is lined between the tips of serrated ends 60a and the opposed end portion of sleeve 18 for insuring a continuous and positive seal when tie 54 is tightened around the arm.

As better illustrated in FIGs. 11 and 12, tie 54 is tightened by ratchetting a sawtooth leader 62 extending from grip 56 through a latch 58. A pawl 66 in the latch, urged by spring 68, engages a sawtooth of leader 62 to

prevent loosening. To effect instant release of tie 54, a cantilevered pushbutton 70 acts against the force of spring 68 to rotate pawl 66 out of engagement to effect instant release of tie 54.

As shown in dotted outline in FIG. 9, when a grip 56 and latch 58 are squeezed toward each other while a surgeon's arm is in cuff 50, tie 54 causes the portion of sleeve 18 between the grip and latch to fold pleat-like as the remaining portion constricts and presses against the surgeon's arm. Pad 64 distributes the pressure more evenly to ensure a good seal.

The embodiment of FIGs. 1-12 represent the most preferred embodiment for carrying out the invention, because the surgeon may readily insert and withdraw his hand several times during the course of surgery. Thus, the FIG. 1-12 embodiment is particularly useful in complex procedures that may require frequent change of instruments.

For less complicated procedures, a version of the invention which does not have all of the features of the embodiments of FIGs. 1-12 may be utilized effectively. To this end, FIGs. 13 and 14 represent such a second embodiment of a surgical apparatus 100 according to the invention. Apparatus 100 comprises a generally elongate cylindrical sleeve 102 of flexible gas-impermeable material like sleeve 18 of FIG. 1 which is closed at a distal end 103 and open at a proximal opposite end 104. An entry opening 114 at end 104 enables a surgeon's hand or surgical instrument to be introduced into sleeve 102. Near distal end 103 there is an exit opening 105 in continuous communication with entry opening 114. A flange 111 is disposed coaxially relative thereto in sealing engagement with sleeve 102. A suitable pressure-sensitive adhesive material on the exposed face of flange 111 is protected by a peel-to-remove cover 112.

An entry sealing means, which for clarity is not illustrated in FIGs. 13 and 14, is indicated generally by a twistable cuff 120 in FIG. 15 integral with a proximal end 104. Cuff 120 includes a first flange 121 and a second flange 122 interconnected by a tubular sealing member 123 of flexible material.

The surgical apparatus 100 of FIGs. 13-17 is used as follows. An incision is first made in the abdomen of a patient without cutting the peritoneum, and the wound hemostatically secured. Incise drape D is applied to the abdomen and an opening made in the drape. Protective cover 112 is removed and flange 111 adhesively bonded to the drape with sleeve exit opening 105 around the incision. If a hand is now inserted through entry opening 114, access to the incision in the abdomen can be achieved via the exit opening 105 as shown in FIG. 17. The interior of sleeve 102 and the abdominal cavity are placed in communication by cutting the peritoneum. Because the wrist of the surgeon's hand effectively occludes entry opening 114, insufflating gas in the abdominal cavity will inflate sleeve 102 like a balloon, preventing gas from escaping. Thus, the abdominal cavity remains in an insufflated condition while appropriate surgery or investigative procedures are carried out. The sealing arrangement at the entry opening of sleeve 102 in FIGs. 15-17 is enhanced by twistable cuff 120 which, by its nature, tends to fully interengage the wrist or arm of the surgeon.

A simplification of the embodiment of FIGs. 15-17 is illustrated in FIG. 18. As seen therein, a surgical apparatus 200 similar in construction to apparatus 100 of FIGs. 13-17 is provided, except that a first flange 251 is integral with a proximal end 204 of a sleeve 202, and a second flange member 252 is integral with a surgeon's glove 253 in the region of the open end thereof. When

the surgeon's arm with glove 253 passes into sleeve 202, flanges 251 and 252 are sealingly interengaged.

FIG. 19 shows still another simplification similar in construction to apparatus 100 of FIGs. 13-17 except sleeve 102 includes a wound protector 261 which is sealingly connected to the exit opening around the site of the incision in the abdomen. Protector 261 includes a tubular member 262 terminating at opposite ends with an inner ring 263 insertable through the incision, and an outer ring 264 peripherally connected to exit opening 105 in sleeve 102. Protector 261 is of the same type material as sleeve 102. Following incision, but before using the apparatus, ring 263 is inserted through the incision, and flange 111 adhesively attached to a drape D.

Referring to FIGs. 20-22, there is shown a surgical apparatus 300 adhering to the abdominal wall L of a patient around wound W. Of course, if a surgical drape were first applied to the operating site, flange 18 would adhere as well to the upper surface of the drape.

Apparatus 300 includes a gas-impermeable, flexible sleeve 312 having a distal end 312a with an exit opening 314 in a bottom panel 312c around wound W sized to pass a surgeon's hand through, and a proximal end 312b with an entry opening 316 remote from the site sized to pass the surgeon's hand through and receive the forearm. A flange 318, fixed to panel 312c around exit opening 314, is coated on the bottom exposed side with an adhesive 319 similar to adhesive 28 supra, for adhering to the abdominal wall L around wound W. An adjustable cuff 320 in entry opening 316 clamps around the forearm to form a chamber in sleeve 312 communicating with the abdominal cavity. An inner gas-lock or duckbill check valve 322 biased normally closed by a bias stay 323, defines an antechamber in sleeve 312 with cuff 320 around the

surgeon's arm to minimize loss of insufflation under conditions of pneumoperitoneum when cuff 320 is breached. Sleeve 312 , valve 322 and cuff 320 are preferably constructed of 3-mil polyolefin with flange 318 of 4-mil polyolefin materials and in the manner of the above-described first embodiment.

Access ports 324 and 326, located near exit opening 314 in a top panel 312d of sleeve 312 allow instruments or the like to be inserted during surgery while maintaining pneumoperitoneum. As best seen in FIG. 21, port 324 defines an opening 324a located approximately coaxial with exit opening 314 and includes a duckbill check valve 324b extending into sleeve 312. An external snap-on cap 324c covers opening 324a when not in use. Access port 326 defines a slot 326a transverse to the length of sleeve 312 between port 324 and distal end 312a and includes a duckbill check valve 326b extending into sleeve 312. A grommet 326c fixed around slot 326a provides stiffening and tear resistance, and a strip 326d coated on one side with a peelable adhesive 326e sealingly adheres to the exposed surface of grommet 326c. On account of the width of duckbill check valve 326a, tension is applied between the opposite sides thereof by a U-shaped stay 326f made of a thin strip of resilient material, such as a high density polyethylene plastic, in order to maintain valve 326a in a normally closed position. Port 324 is sized to pass slender instruments such as lumens and trocars, whereas port 326 is sized to pass wider instruments such as clamps and forceps. The duckbill configuration of the check valve 324 and 326 comprises two flexible flat panels joined to each other on opposite sides and around the respective specimens 324a and 326a.

A wound protector 13, supra, emplaced in exit opening 314 and extending through abdominal wall L and

peritoneum P, protects wound W from exposure to diseased tissue and non-sterile material passing through the wound during surgery.

Referring now to FIG. 23, there is shown a surgical apparatus, indicated generally by the numeral 330, which is especially suitable for obtaining an asceptic environment in the immediate vicinity of wound W for performing emergency abdominal surgery such as at a mobile field hospital. Apparatus 330 comprises a flexible enclosure 332 made of a generally flat bottom panel 332a covered by a dome-shaped top panel 332b. An exit opening 334 in bottom panel 332a includes an adhesive flange 336 for sealing to surgical drape D around an aforedescribed wound protector 13 emplaced in wound W. A distal end of flexible left and right sleeves 338a and 338b, respectively, communicate with the interior of enclosure 332 through openings in top panel 332b on generally opposite sides thereof. Entry openings 340 at proximal ends of sleeves 338a and 338b each includes an aforedescribed adjustable cuff 320 which tightens around the surgeon's forearms and completely isolates wound W from ambient conditions.

Top panel 332b of enclosure 332 includes access ports 344 constructed like access port 324 of FIG. 21 for passing instruments through to the surgeon. The size of the port is determined according to the size and shape of the instruments. In addition, pockets 346 affixed to the interior of top panel 332b are provided for storing instruments and other devices at easily accessible locations. The shape of the pockets depend on the type of device stored.

Top panel 332b is preferably made of a thin transparent plastic film to give the surgeon a clear view of the operating site. Apparatus 330 being made of flexible material allows the surgeon in a field emergency

situation to close wound W temporarily and roll up sleeves 338a and 338b, as shown in broken outline, thereby sealing enclosure 332 for transporting the patient to another facility with apparatus 330 attached where the surgery can be completed under better conditions. Elastic bands or clips, not shown, may be applied to keep the sleeves from unrolling.

Referring now to FIG. 24, there is shown a surgical apparatus, indicated generally by the numeral 350, for hand-assisted minimum invasive surgery under conditions of pneumopentoneum which can be readily connected and disconnected by the surgeon during the operation. Apparatus 350 comprises a sleeve 352 having an entry opening 354 at a proximal end which is tightened around a surgeon's forearm by an adjustable cuff 320 as described in FIG. 20. An elastic ring 356 at the distal end of sleeve 352 defines an annular lip 356a with an interference fit with the outer O-ring 16 of wound protector 13, which has been emplaced in wound W in the manner heretofore described. An adhesive-coated flange 358 about ring 356 adheres to surgical drape D to sealingly enclose sleeve 352 about the wound.

Ports 360 and 362 provide direct access for instruments to be inserted into sleeve 352 without losing insufflation pressure, if any is present. Port 360 is constructed with check valves 360b and snap on cap 360C in the same manner as port 324 of FIG. 20. Port 362 is preferably constructed of a semi-rigid sleeve 362a communicating at one end through an opening 362b in sleeve 352. A duckbill valve 362c extends toward opening 362b from an O-ring 362d secured around the other end of sleeve 362a.

The methods of using the several embodiments of FIGs. 20-24 of the surgical apparatus are similar to the aforedescribed methods. Basically, the abdomen is

routinely prepared with anteseptics and dried, and incise drape D is applied to the operating site. An incision with a scalpel is made at the site of sufficient size for a surgeon's hand to pass through. Wound protector 13 corresponding in size with the incision is placed in the wound by squeezing one O-ring into a tight ellipse and inserting it lengthwise through the incision until it expands inside the peritoneum and the O-ring on the other end overlaps the exposed drape D around wound W. With the surgeon's hand extending into the abdominal cavity through the wound protector 13, trocars/cannulas may be guided into place and the hand removed in order to attach one of the above-described surgical apparatus 300, 330, or 350. The hand is then reinserted through the openings of the apparatus and the cavity insufflated. Instruments and other materials may then be inserted within easy reach of the surgeon's hand through the various ports, or may be stored in pockets within the apparatus.

Some of the many novel features and advantages of the invention should now be readily apparent. Because hand-assisted laparoscopic techniques allow a surgeon to make only a relatively small incision, the trauma to the patient is minimized. There is less risk of damage to the immune system, healing time is shortened as well as the length of a hospital stay. A wider range of operations can be performed using an apparatus according to the invention. Conventional hand surgery in combination with laparoscopic techniques considerably simplifies procedures enabling them to be readily performed by a surgeon with minimal additional training. This is because the transition to hand-assisted laparoscopic surgery is relatively easy for a surgeon who is already trained in conventional hand surgery.

Additionally, or alternatively, an adhesive-backed flange may be placed around the exit opening of the

sleeve, and in some cases adhesive may be applied to the patient around the area of the incision where the sealing flange is to be attached. Either or both adhesive may be covered by sterile wrapping material through which the incision can be made; and either or both layers of adhesive may be provided with peel-to-remove covers. A unique cuff for design is also provided which enables a surgeon to quickly seal or release his arm or a surgical instrument extending through an entry opening of a surgical enclosure. It is also contemplated that the sleeve may be easily modified to accommodate the use of both arms if required.

A surgical apparatus is also provided which is especially suitable for open or minimum invasive surgery while maintaining a sterile asceptic environment at the operating site. Ports with duckbill check valves allow instruments of various shapes and sizes to be inserted under conditions of pneumoperitoneum and within easy reach of the surgeon's hand. The apparatus can be quickly disconnected and reconnected around the site of an incision to accommodate brief interruptions in the course of an operation. In one of the disclosed embodiments, the apparatus can remain attached to the patient while being transferred from a field hospital to a more complete operating room facility where the surgery can be completed.

It will be understood, of course, that changes in details, steps and arrangement of parts which have been herein described and illustrated in order to explain the nature of the invention, may be made by those skilled in the art within the principle and scope of the invention as expressed in the appended claims.

Claims

1. Apparatus (10) for use in surgery comprising:
an outer sleeve (18) of gas-impermeable supple material and having an entry opening (23a) at a proximal end (18e) thereof and an exit opening (24) at a distal end (18c) thereof;
first sealing means for sealing the exit opening (24) around an incised wound in a patient; and
second sealing means for sealing the entry opening (23a) to create a gastight chamber in said outer sleeve (18) when a surgeon's arm is operatively received in said sleeve (18);
whereby the sleeve (18) cooperates with the first and second sealing means to enable surgery to be performed under insufflatable conditions.

2. Apparatus (10) according to claim 1 further comprising:
third sealing means interposed in said sleeve (18) between said first and second sealing means for maintaining the gastight chamber with the wound when said second sealing means is breached.

3. Apparatus (10) according to claim 2 wherein:
said third sealing means includes an inner sleeve having a proximal end sealingly joined at facing portions to said outer sleeve (18) and a distal end (18c) forming a normally closed aperture which opens automatically in response to movement of an object from proximal to distal locations therethrough.

4. Apparatus (10) according to claim 3 wherein:
said third sealing means further includes a resilient means connecting the proximal end of said inner sleeve to said outer sleeve (18) for biasing said aperture to a normally closed position.

5. Apparatus (10) according to claim 1 wherein:
said first sealing means includes a flexible flange (26) secured around said exit opening (24) and having an exposed face for attaching around the wound.

6. Apparatus (10) according to claim 5 further comprising:
an adhesive coating (28) on said exposed face for adhering said flange (26) around the wound.

7. Apparatus (10) according to claim 6 wherein:
said adhesive coating (28) comprises an acrylate polymer of about 0.002 in. thickness, approximate physical properties of peel adhesion 8 to 10 lb/in^2, shear resistance of 1.2 hrs. at 1 kg/in^2, and tack 1250 g/cm^2.

8. Apparatus (10) according to claim 6 further comprising:
a peel-off strip (30) covering said adhesive coating (28).

9. Apparatus (10) according to claim 1 wherein:
said entry (23a) and exit (24) openings are formed to accommodate a surgeon's hand and forearm.

10. Apparatus (10) according to claim 1 wherein: said entry (23a) and exit (24) openings are formed to accommodate instrumentarium.

11. Apparatus (10) according to claim 1 wherein: said material is sufficiently flexible for effecting a wide range of arm movement at said entry opening (23a) relative to said exit opening (24).

12. Apparatus (10) according to claim 1 further comprising:
a wound protector means (12) insertable in the wound for simultaneously lining said exit opening (24) and the wound.

13. Apparatus (10) according to claim 12 wherein said wound protector means (12) further comprises:
a pair of generally coaxial resilient rings (14,16) contiguously connected to respective ends of a flexible tube (13), one of said rings (16) being formed to compress said tube (13) within said outer sleeve (18) around said exit opening (24), and the other of said rings (14) being formed to compress said tube (13) around the internal side of the wound.

14. Apparatus (10) according to claim 13 wherein said tube (13) is made of a supple material effectively impermeable to gases and microorganism-bearing fluids.

15. Apparatus (10) according to claim 13 wherein: said tube (13) is sized for contiguous contact with the wound.

16. Apparatus (10) according to claim 1 wherein said second sealing means comprises:
an inflatable tube (20) fixed around the proximal end (18e) of said outer sleeve (18); and
an elastic inflator (22) operatively connected to said tube (20) for inflating said tube (20) in compression around the surgeon's arm or instrument.

17. Apparatus (10) according to claim 1 wherein said second sealing means comprises:
a track formed around the proximal end (18e) of said outer sleeve (18);
a clamp tie (54) having a U-shape strip (60) slidable in said track with an exposed finger grip (56) at one end and an exposed latch (58) at the other end, and a sawtooth leader (62) slidable in said strip (60) extending from said grip (56) for engaging said latch (58).

18. Apparatus (10) according to claim 17 wherein said clamp tie (54) further comprises:
an elastic pad (64) interposed between said strip (60) and said outer sleeve (18) for enhancing contiguity of engagement between said outer sleeve (18) and the surgeon's arm.

19. Apparatus (10, 100) according to claim 1 wherein:
said second sealing means includes a pair of flanges (121, 122) interconnected on a common axis by a supple tube (123), said flanges (121, 122) being relatively adjustable about said axis for twisting said tube (123) into a constricting position around an object.

20. Apparatus (10, 100) according to claim 19 wherein;
said flanges (121, 122) include means for locking said flanges (121, 122) together in the constricting position.

21. Apparatus (10, 200) according to claim 1 wherein:
said second sealing means includes a first flange (251) secured around said entry opening, a surgical glove (253) for inserting into said outer sleeve through said first flange (251), and a second flange (252) secured around the opening of said glove (253) for sealing attachment to said first flange (251).

22. A cuff (50) for positively sealing around an arm or instrument extending through an entry opening (23a) of a surgical enclosure, comprising:
a track formed around the entry opening (23a) of the surgical enclosure;
and a clamp tie (54) having a U-shaped strip (60) slidable in said track with an exposed finger grip (56) and latch (58) at opposite ends, a sawtooth ratchet (62) extending from said grip (56) slidable in said strip (60) for engaging said latch (58).

23. A cuff (50) according to claim 22 further comprising:
an elastic pad (64) interposed between said strip (60) and the entry opening (23a) of the surgical enclosure for enhancing contiguity of engagement between the entry opening (23a) and a surgeon's arm.

24. A method for hand-assisted laparoscopic surgery in pneumoperitoneum comprising the steps of:
incising a wound in the abdomen and peritoneum;
inserting a hand through the incision into the abdominal cavity;
puncturing trocar/cannula assemblies through the peritoneum at desired sites using the hand as a guide to protect internal organs;
removing the hand from the cavity;
applying a gas-impermeable sleeve (18) around the incision to provide a controlled environment communicating with the cavity;
insufflating the cavity to create pneumoperitoneum;
inserting a hand through a cuff (20) in the sleeve (18) while retaining insufflation; and
completing the surgery.

25. A method according to claim 24 wherein:
said incising step includes placing a template on the abdomen and marking the incision site relative to the puncture sites.

26. A method according to claim 24 further comprising:
after the incising step, inserting an expansible protecting liner (12) in the wound, the liner (12) including a first flexible ring (14) inside the cavity and a second flexible ring (16) outside the cavity; and
the applying step includes interposing the sleeve (18) between the outside of the abdomen and the second flexible ring (16).

27. A method according to claim 24 further comprising:
before incising the peritoneum, placing an incise drape over the abdomen.

28. A method for minimally invasive surgery comprising the steps of:
incising a body cavity sufficient for passing one hand therethrough;
applying the distal end (18c) of a gas-impermeable sleeve (18) around the incision to provide a controlled environment communicating with the cavity;
insufflating the cavity;
inserting the hand and arm through a cuff (20) in the sleeve (18) while retaining insufflation.

29. A method according to claim 28 further comprising:
after the incising step, inserting an expansible liner (12) in the wound formed thereby, the liner (12) including a first flexible ring (14) inside the cavity and a second flexible ring (16) outside the cavity; and
the applying step including interposing the distal end (18c) of the sleeve (18) between the outside of the incision and the second flexible ring (16).

30. Apparatus (10) for use in laparoscopic surgery in a sufflatable body cavity having an outer surface, comprising:
an elongate flexible sleeve (18) having an end portion (18c) positionable adjacent the body cavity and a proximal end portion (18e) positionable away from the body;

means defining an exit opening (24) laterally of said flexible sleeve (18) adjacent to said distal end portion (18c);

means defining an entry opening (23a) co-axially of said flexible sleeve (18) at said proximal end portion (18e);

first sealing means carried by said sleeve (18) and surrounding said exit opening (24) and adapted to engage said body outer surface;

second sealing means carried by said sleeve (18) and surrounding said proximal end portion (18e) for sealingly engaging a surgeon's arm; and

means in said sleeve (18) between its distal (18c) and proximal (18e) end portions providing a normally-closed flexible valve (32) openable upon insertion of the surgeon's hand toward the distal end portion (18c) of the sleeve (18) and automatically closeable upon withdrawal of the surgeon's hand, said valve (32) providing a third sealing means cooperable with said first sealing means to define a substantially gastight chamber in communication with said exit opening (24);

whereby the surgeon can readily insert and withdraw his hand from the body cavity in the course of surgery without significant loss of pressure in the body cavity when sufflated.

31. Apparatus (10) according to claim 30 wherein said normally closed valve (32) is of the duckbill type formed by at least one flexible panel (32a, 32b) secured to said sleeve (18) and providing an aperture (34) at a location adjacent to said exit opening (24).

32. Apparatus (10) according to claim 31 including resilient means carried by said sleeve (18) for biasing said at least one panel (32b) in a direction to close said aperture (34).

33. Apparatus (10) according to claim 31 wherein said valve (32) includes another panel (32a) like said first mentioned panel (32b) and juxtaposed in said sleeve (18) therewith for cooperating therewith to form an elongate slot (33) openable to provide said aperture (34).

34. Apparatus (10) according to claim 30 wherein said means defining an exit opening (24) includes an annular flange (26) having an adhesive coating (28) for securing the sleeve (18) to the body outer surface with the sleeve (18) extending alongside the body.

35. Apparatus according to claim 34 wherein:
said adhesive coating (28) comprises an acrylate polymer of about 0.002 in. thickness, approximate physical properties of peel adhesion 8 to 10 lb/in^2, shear resistance of 1.2 hrs. at 1 kg/in^2, and tack 1250 g/cm^2.

36. Apparatus (10) according to claim 30 including a flexible, tubular wound protector (12) depending from said means providing said exit opening (24) for insertion into a wound formed in said outer surface, said wound protector (12) including a flexible membrane (13) mounting annular elastic rings (14, 16) at opposite ends.

37. Apparatus (10) according to claim 30 wherein said proximal end (18e) second sealing means gastightly engages the periphery of the surgeon's arm when his hand is inserted in the sleeve (18).

38. Apparatus (10) for use in laparoscopic surgery in a gas sufflatable body, comprising:
an elongate flexible sleeve (18) having a lateral exit opening (24) at one location and an axial entry opening (23a) at another location;
first means for gastightly sealing said sleeve (18) around said exit opening (24) to a body surface undergoing laparoscopic surgery;
second means for gastightly sealing said sleeve (18) around a surgeon's arm adjacent to said entry opening (23a); and
means providing a duckbill check valve (32) in said sleeve (18) for preventing gas flow from said exit opening (24) to said entry opening (23a) when said second sealing means is unsealed;
whereby a surgeon may insert and withdraw his hand through the exit opening (24) without significantly affecting gas pressure in the sufflated body.

39. Apparatus (10, 300) according to claim 1 further comprising:
at least one port means (324, 326) in said sleeve (312) proximal to said exit opening (314) formed to maintain effective isolation of the wound while passing surgical instruments through said port means (324, 326) into said chamber.

40. Apparatus (10, 300) according to claim 39 wherein:

said port means (324, 326) includes a first aperture (324a) disposed in said sleeve (312) oppositely from said exit opening (314), and a first duckbill check valve (324b) connected to said sleeve (312) for communicating between said first aperture (324a) and said chamber.

41. Apparatus (10, 300) according to claim 40 further comprising:

a snap-on cap means (324c) connected to said port means (324) for manually closing said first aperture (324a).

42. Apparatus (10, 300) according to claim 40 wherein:

said first check valve (324b) is formed to pass lengthwise slender surgical instruments, including trocars and lumens.

43. Apparatus (10, 300) according to claim 39 wherein:

said port means (326) includes an elongate second aperture (326a) disposed in said sleeve (312) near the distal end (312a) and athwart the length thereof, and a second duckbill check valve (326b) connected to said sleeve (312) for communicating between said second aperture (326a) and said chamber.

44. Apparatus (10, 300) according to claim 43 further comprising:

grommet means (326c) lining said second aperture (326a) for providing stiffness and tear resistance thereto, and

a peelable strip (326d, 326e) adhesively secured to the exposed surface of said grommet (326c) for manually closing said second aperture (326a) to the ambient conditions.

45. Apparatus (10, 300) according to claim 43 wherein:

said second check valve (326b) is formed to pass lengthwise wide instruments, including forceps and clamps.

46. The improvement according to claim 39 wherein:

said port means (324, 326) includes a plurality of apertures (324a, 326a) in said sleeve (312) disposed in close proximity to said exit opening (314), and a duckbill check valve (324b, 326b) connected to said sleeve (312) communicating between each of said apertures (324a, 326a) and said chamber.

47. The improvement according to claim 46 wherein:

said first and second check valves (324b, 326b) each comprise two flexible panels with opposite congruent side edges respectively joined together, and one end of said panels joined to said sleeve (312) around respective ones of said apertures (324a, 326a).

48. Apparatus (330) for enabling surgery with two hands with isolation at the site of a wound from ambient conditions comprising, in combination:

a dome-shaped gas-impermeable enclosure (332) having a centrally disposed exit opening sealable around the wound; and

at least two gas-impermeable sleeves (338a, 338b), each sleeve (338a, 338b) communicating at a distal end thereof through an opening with the interior of said enclosure (332), and an entry opening (340) at a proximal end thereof sealable about the forearm of a hand extended therein forming thereby a gas-tight chamber with said enclosure (332).

49. Apparatus (330) according to claim 48 further comprising:

at least one port means (344) formed in said enclosure (332) proximal to said exit opening (334) for effectively maintaining isolation while passing surgical instruments through said port means (344) into said chamber.

50. Apparatus (330) according to claim 49 wherein:

said port means (344) includes an aperture disposed in said enclosure (332), and a check valve connected to said enclosure (332) for communicating between said aperture and said chamber.

51. Apparatus (330) according to claim 50 wherein:

said check valve is formed to pass surgical instruments through.

52. Apparatus (330) according to claim 50 further comprising:

a snap-on cap connected to said port means (344) for manually closing said aperture.

53. A surgical apparatus (350) for hand-assisted surgery with isolation at the site of a wound from ambient conditions, comprising:

a sleeve (352) of gas-impermeable supple material having an entry opening (354) at a proximal end thereof and an exit opening at a distal end thereof;

first sealing means formed to seal the exit opening around the wound;

second sealing means formed to seal the entry opening (354) around a surgeon's forearm to create a gastight chamber in said sleeve (352); a wound protector (13) including a flexible tube formed to line the wound, said tube having resilient rings at respective ends thereof, for stretching the ends of said tube around the internal and external surfaces of the wound; and

an annular lip (356a) formed at the distal end of said sleeve (352) having an interference fit formed to snap onto said ring at the external end of said tube.

54. Apparatus (350) according to claim 53 further comprising:

a flexible flange (358) recessed around said lip (356a) and having an exposed face for attaching around the site of the wound.

55. The improvement according to claim 53 further comprising:

at least one port means (360, 362) formed in said sleeve (352) proximal to said exit opening for effectively maintaining isolation while passing surgical instruments through said port means (360, 362) into said chamber near the site of the wound.

56. The improvement according to claim 55 wherein:

said port means (360) includes an aperture disposed in said sleeve (352) oppositely from said exit opening, and a duckbill check valve (360b) connected to said sleeve (352) for communicating between said aperture and said chamber.

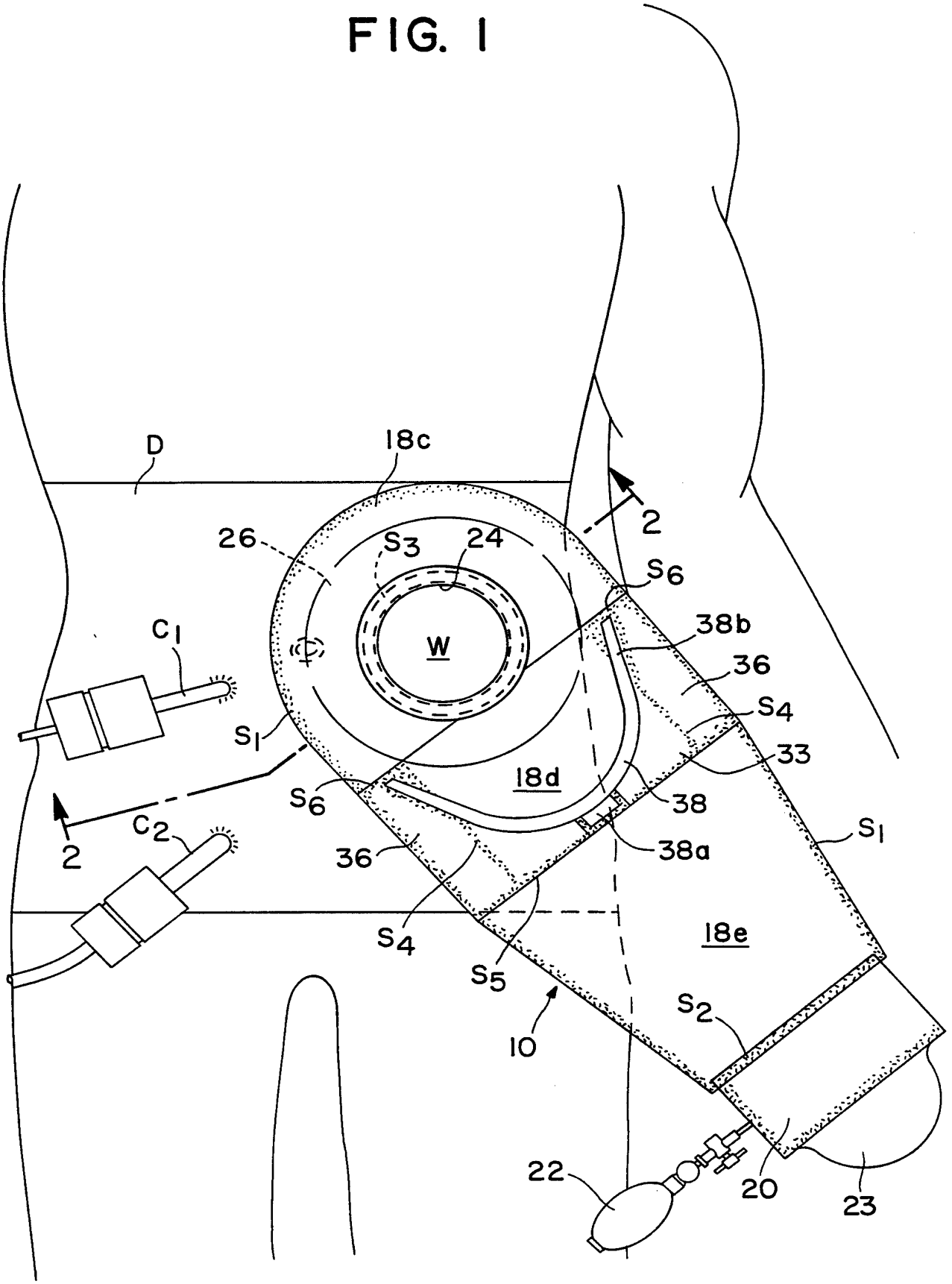
57. The improvement according to claim 55 further comprising:

a snap-on cap means (360c) connected to said port means (360) for manually closing said aperture.

58. The improvement according to claim 56 wherein:

said check valve (360b) is formed to pass lengthwise slender surgical instruments, including trocars and lumens.

FIG. 1


D
18c
2
26
S3
24
S6
38b
36
S4
33
C1
W
S1
18d
38
S1
S6
2
C2
36
38a
S4
18e
S5
S2
10
22
20
23

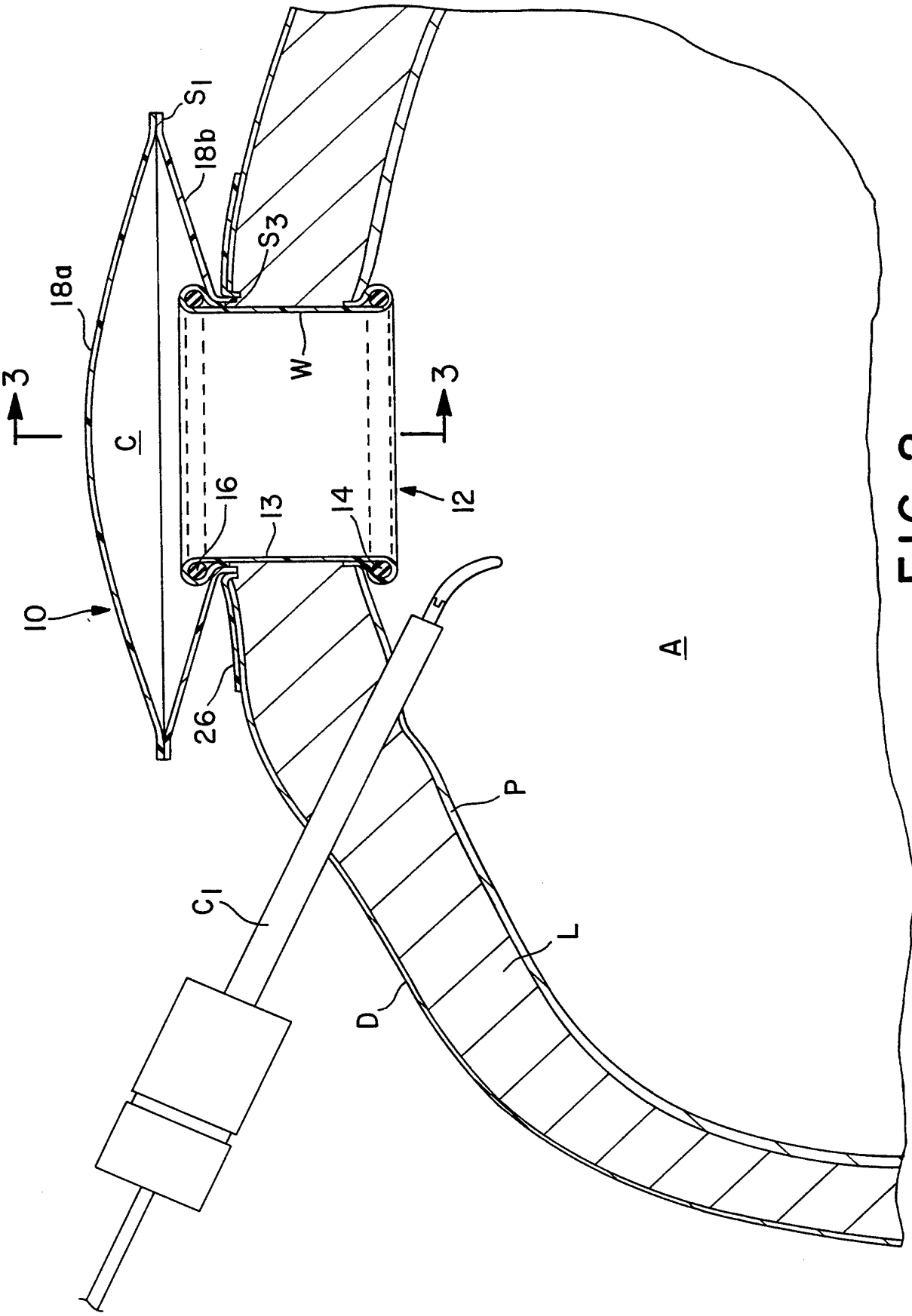


FIG. 2

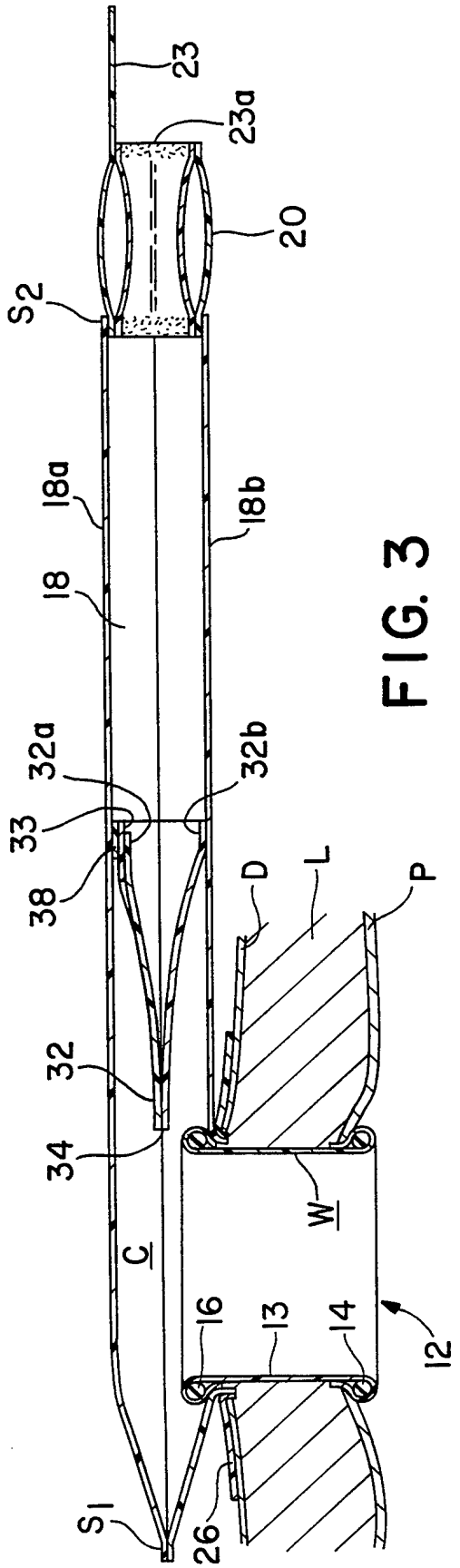


FIG. 3

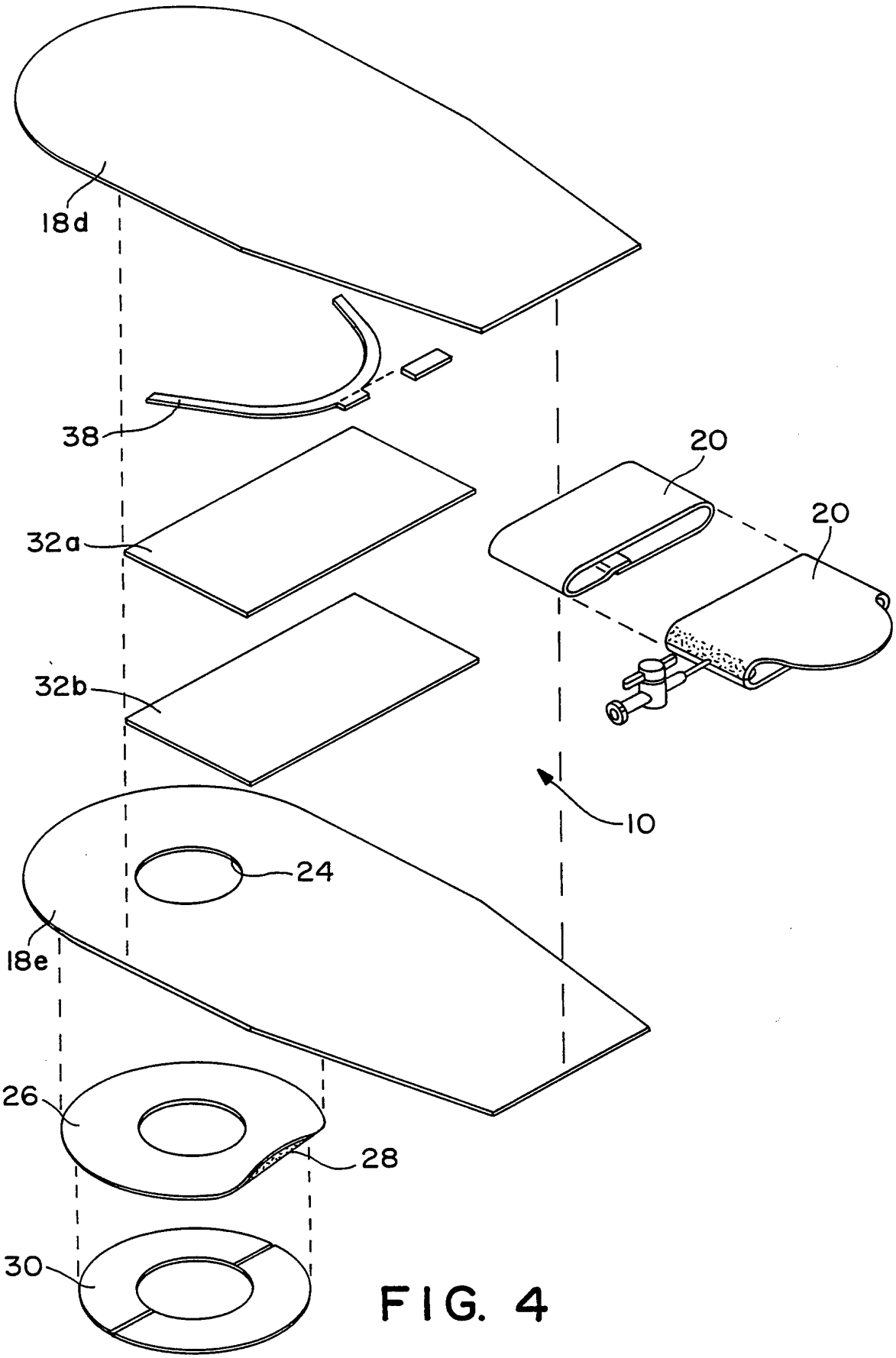


FIG. 4

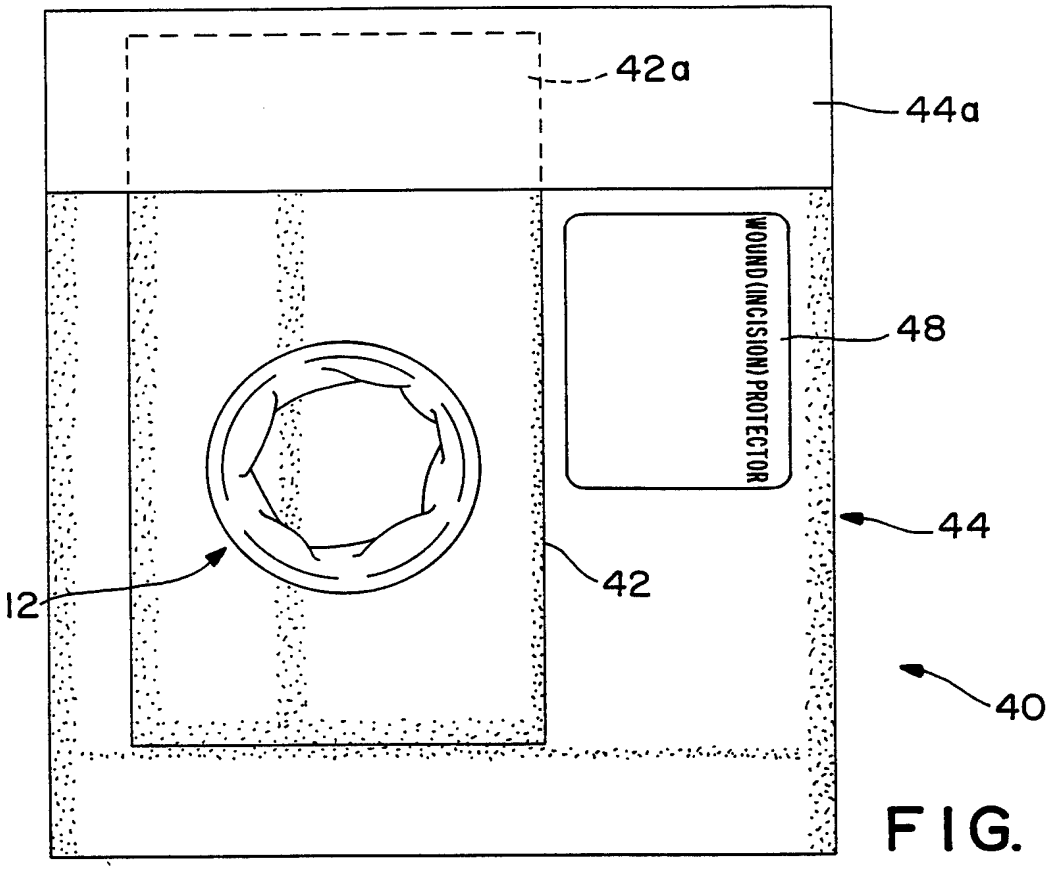

42a
44a
WOUND (INCISION) PROTECTOR
48
44
12
42
40

FIG. 5

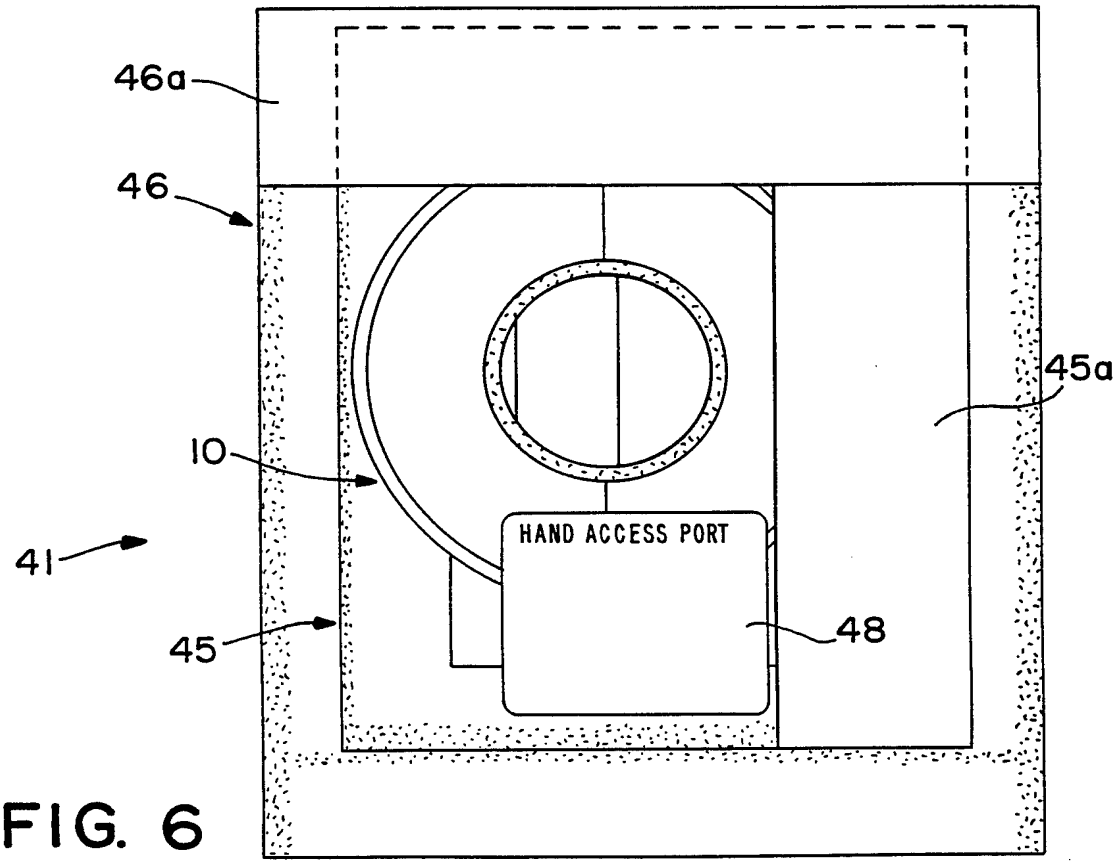

46a
46
45a
10
41
HAND ACCESS PORT
45
48

FIG. 6

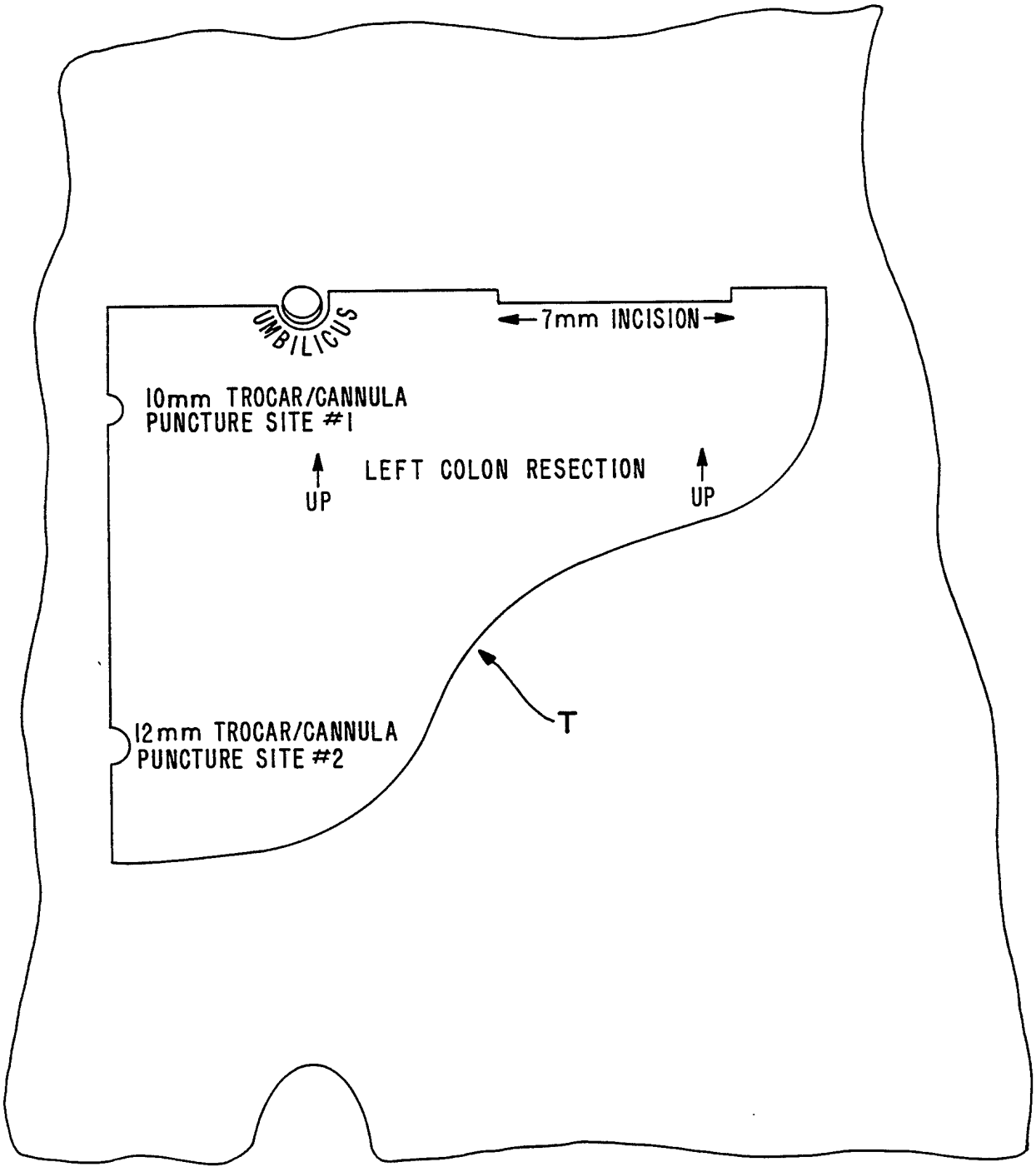

UMBILICUS
7mm INCISION
10mm TROCAR/CANNULA
PUNCTURE SITE #1
UP
LEFT COLON RESECTION
UP
T
12mm TROCAR/CANNULA
PUNCTURE SITE #2

FIG. 7

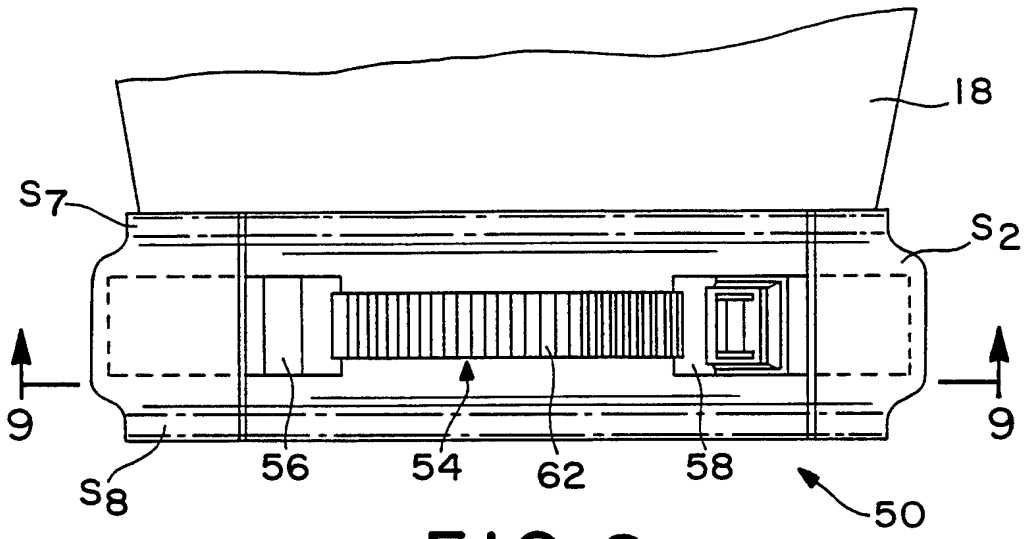

18
S7
S2
9
9
56
54
62
58
S8
50

FIG. 8

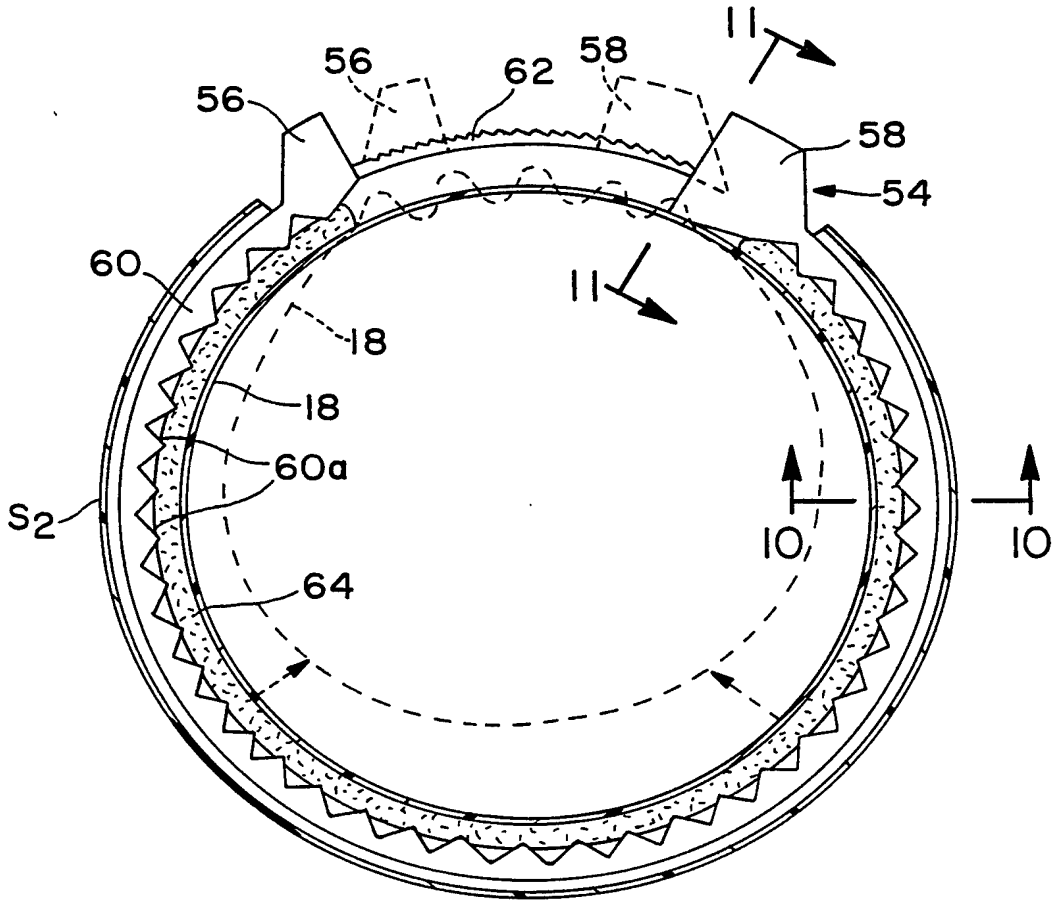

11
56
62
58
56
58
54
60
11
18
18
60a
S2
10
10
64

FIG. 9

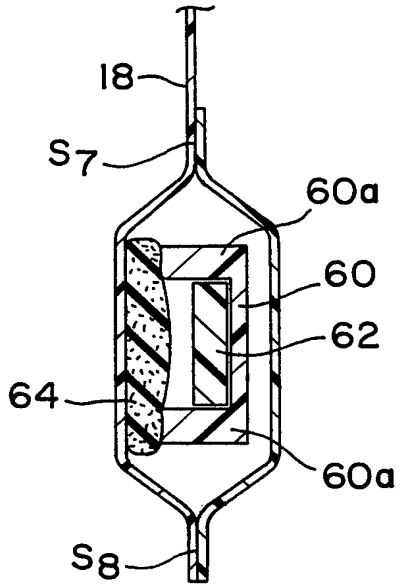


FIG. 10

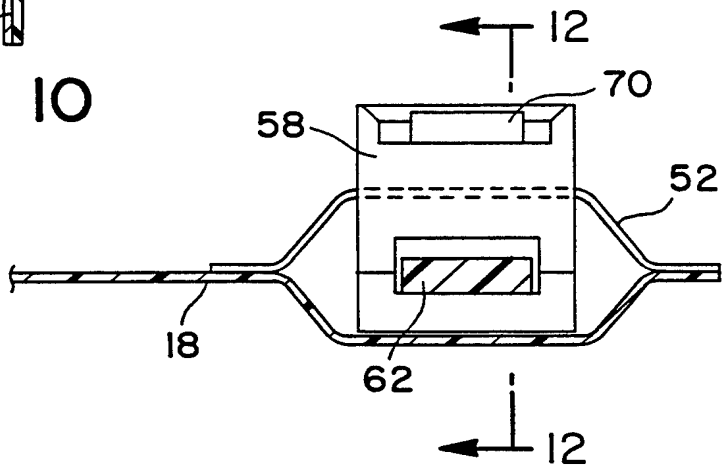


FIG. 11

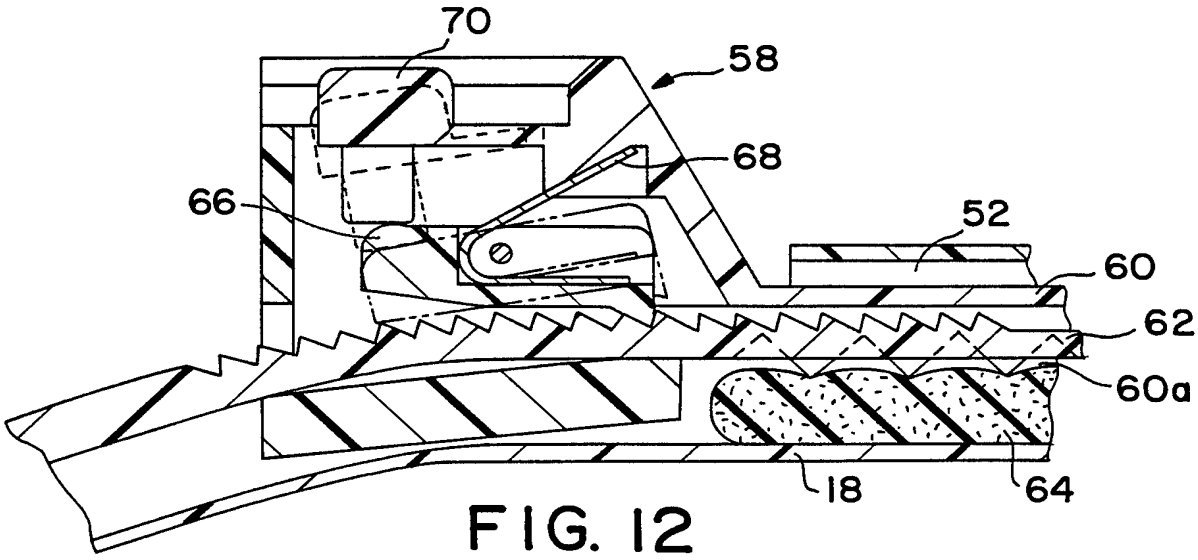


FIG. 12

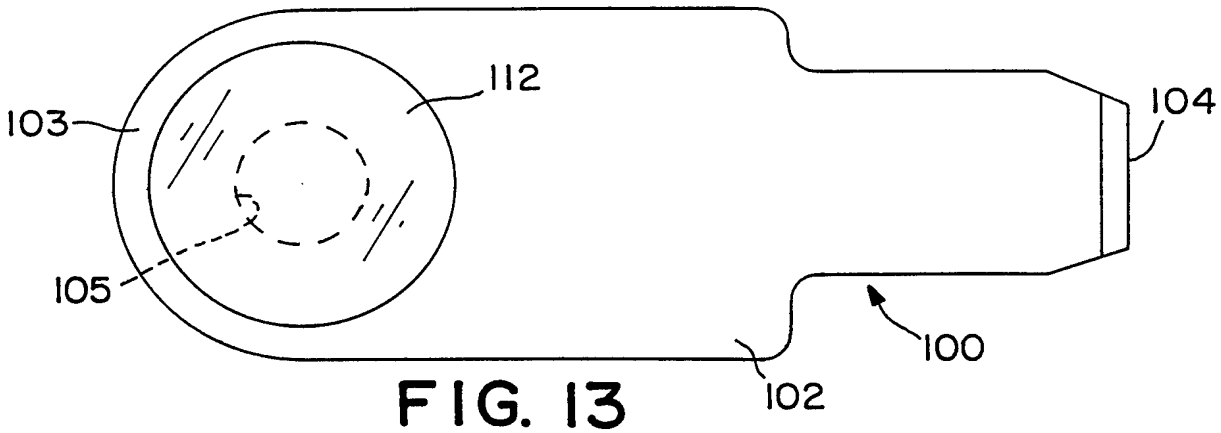


FIG. 13

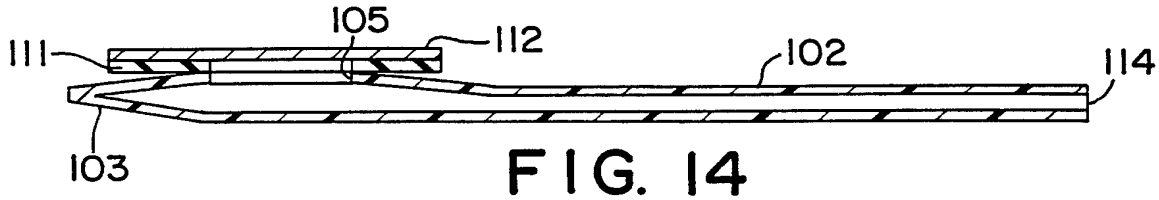


FIG. 14

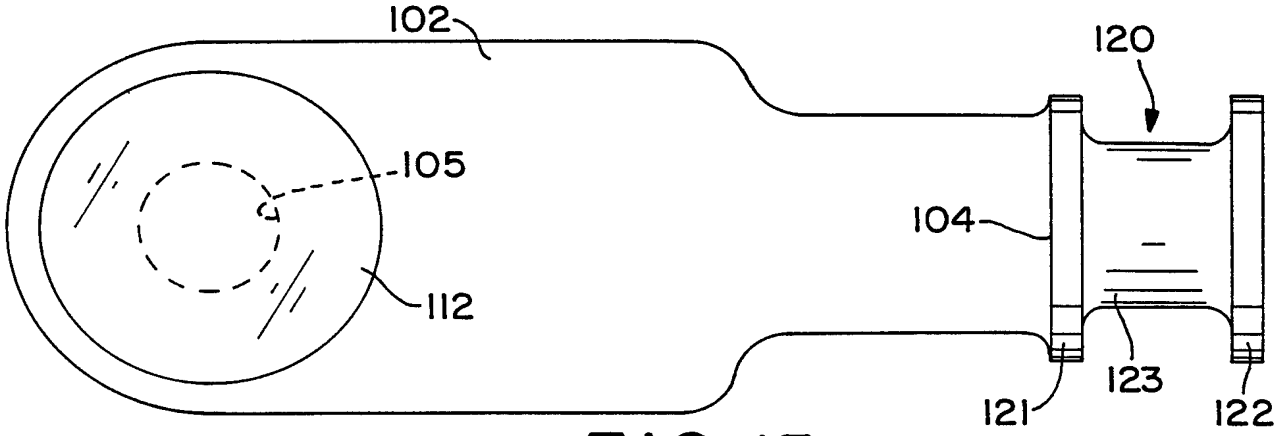


FIG. 15

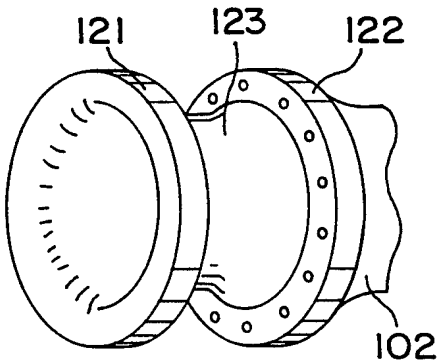


FIG. 16A

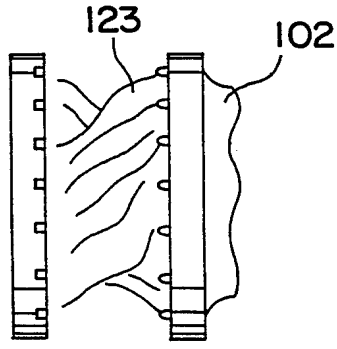


FIG. 16B

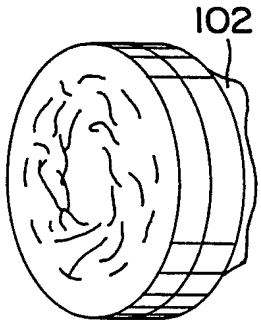


FIG. 16C

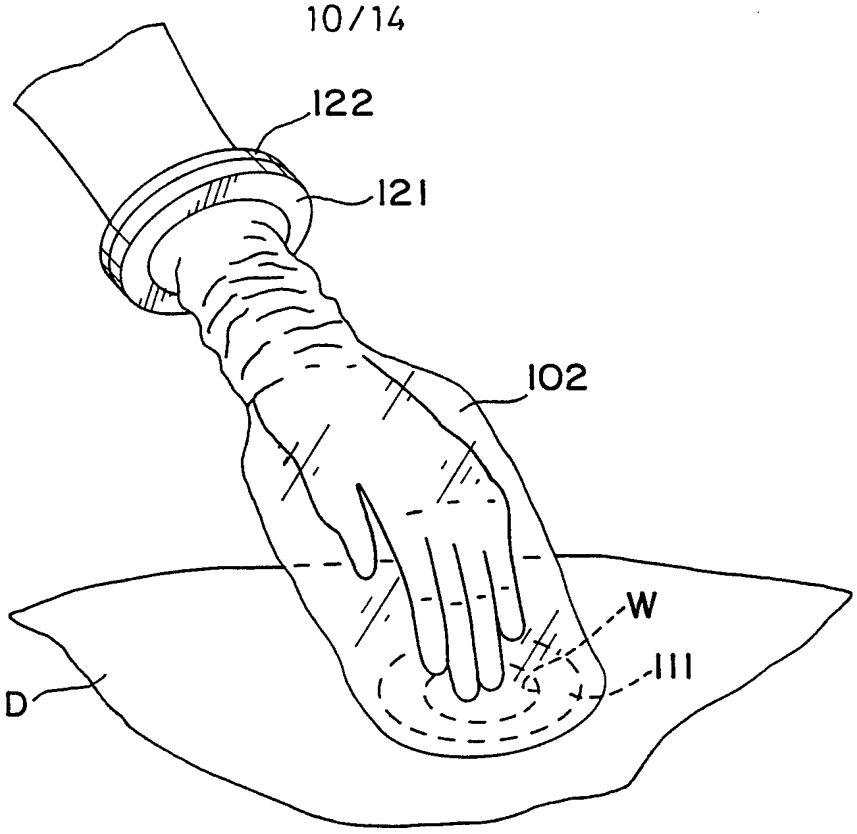


FIG. 17

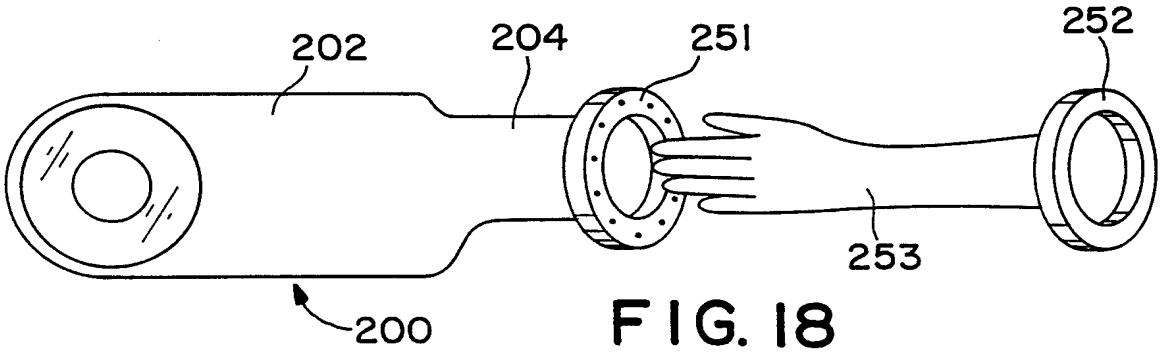


FIG. 18

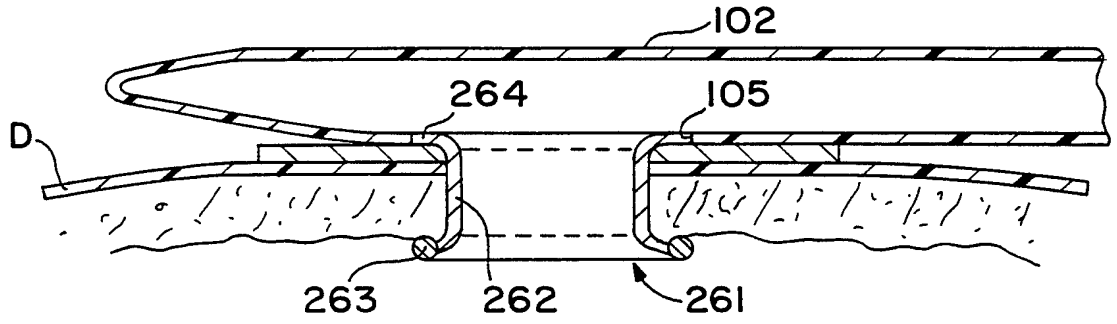


FIG. 19

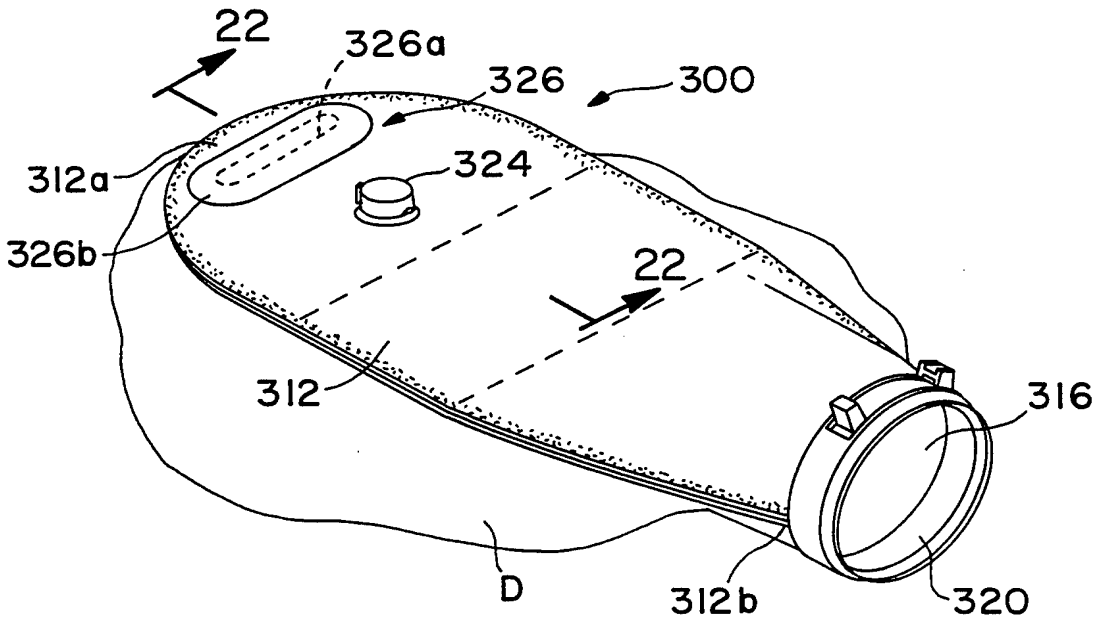

22
326a
326
300
312a
324
326b
22
312
316
D
312b
320

FIG. 20

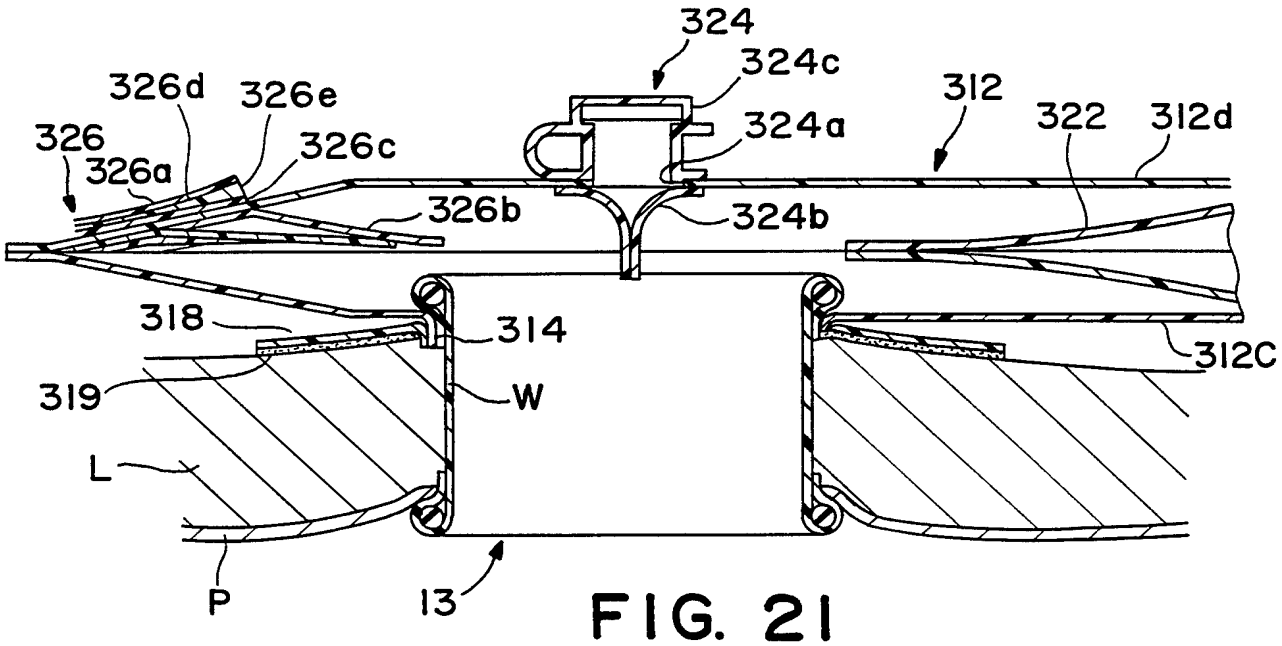

324
324c
326d
326e
312
322
312d
326
326a
326c
324a
326b
324b
318
314
312C
319
W
L
P
13

FIG. 21

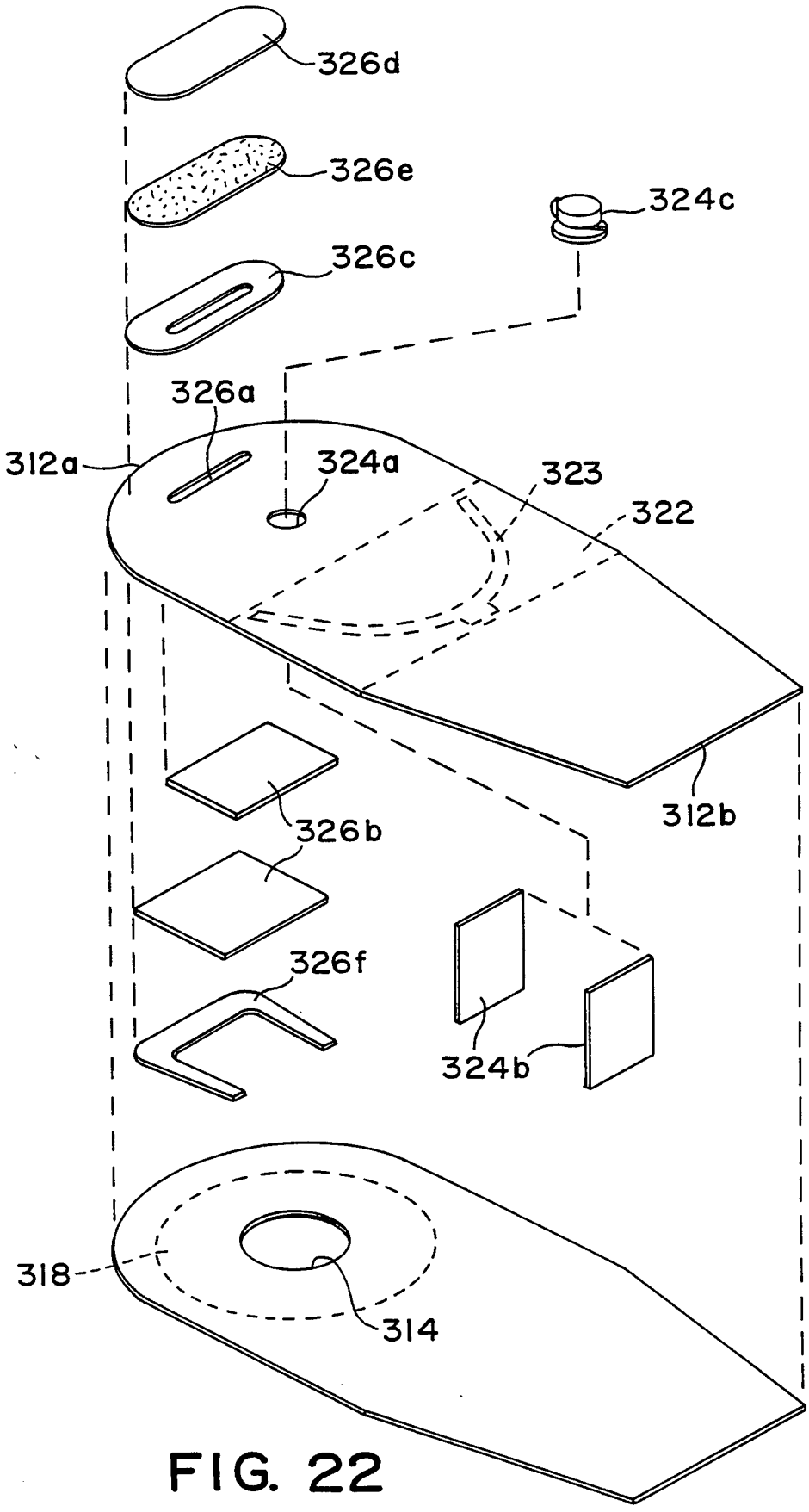
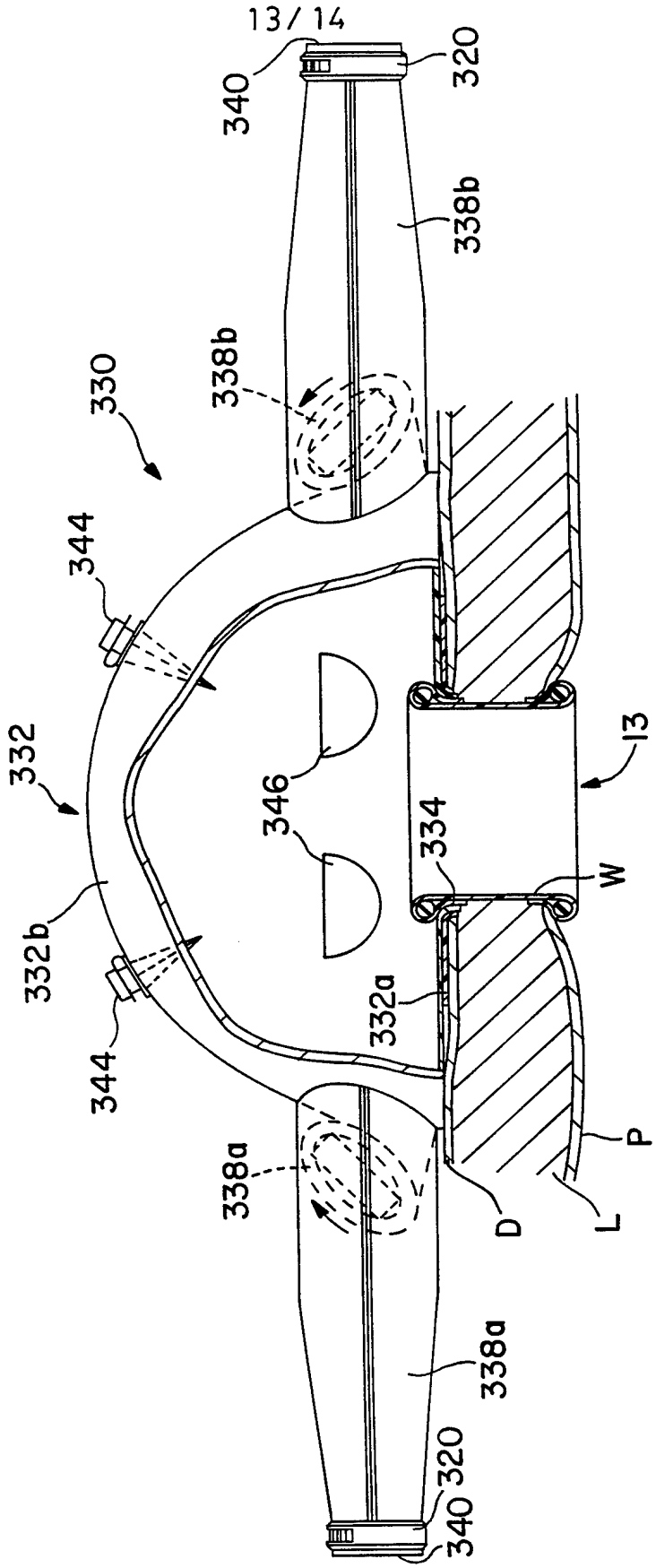

326d
326e
324c
326c
326a
312a
324a
323
322
312b
326b
326f
324b
318
314

FIG. 22


340
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338b
338b
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332
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334
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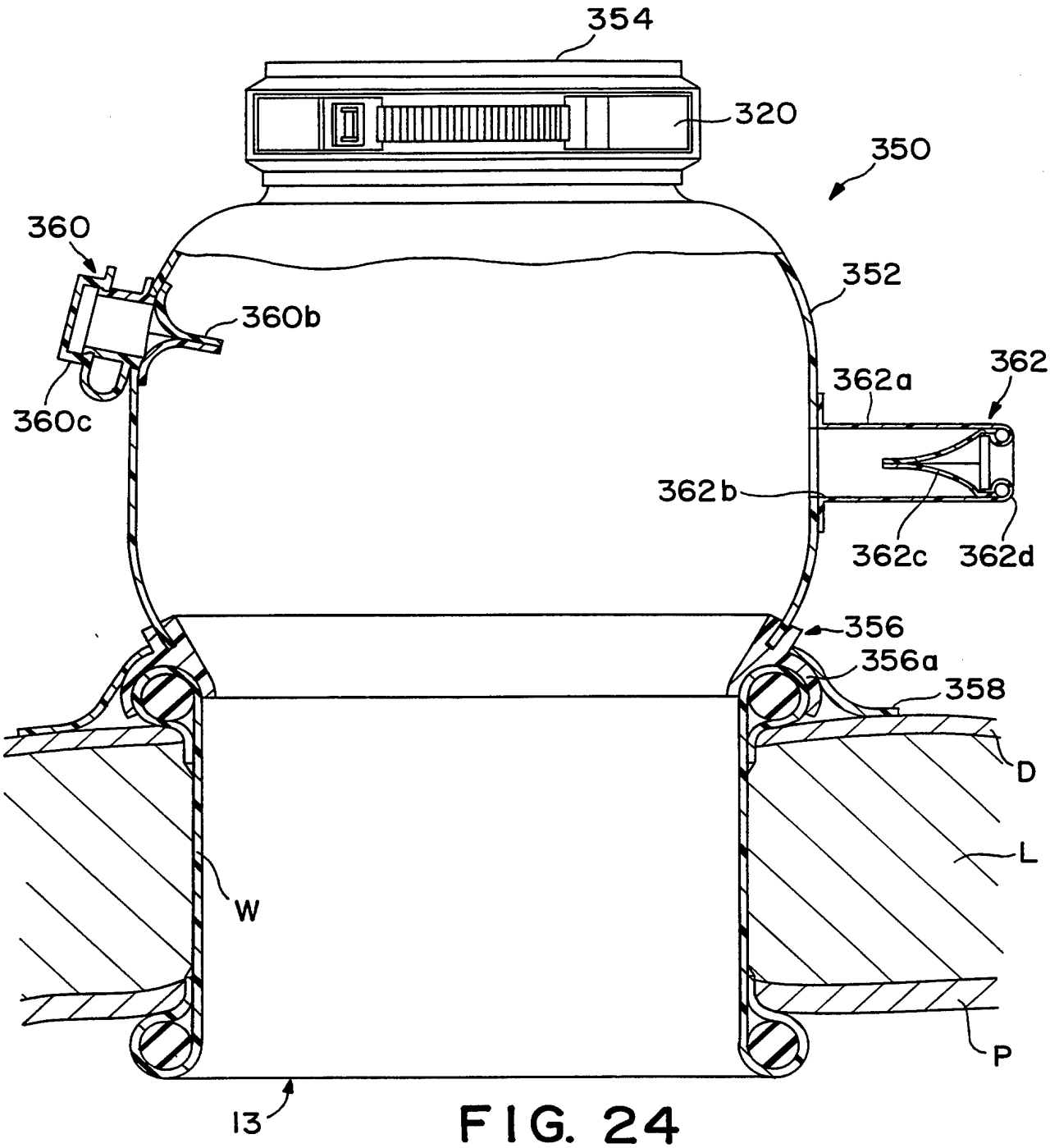
332b
332a
344
338a
P
D
L
338a
320
340

FIG. 23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352
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362b
362c
362d
356
356a
358
D
L
W
P
13

FIG. 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/04202

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61G 10/00
US CL :600/021

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/846-853, 897, 898; 600/021

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,926,882, (LAWRENCE), 22 May 1990. See entire document.	1. 10, 11, 48
X	US, A, 3,523,534, (NOLAN), 11 August 1970. See entire document.	1, 11, 48
X	US, A, 5,299,582, (POTTS), 05 April 1994. See entire document.	1, 9, 11, 48
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Y		12-15
Y	US, A, 3,332,417, (BLANFORD ET AL.), 25 July 1967 See entire document.	12-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

25 JUNE 1995

Date of mailing of the international search report

18 JUL 1995

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